

## REMARKS

In response to the Office Action of November 17, 2003, claim 13 is hereby amended. Claims 13, 15-16, 19, 23 and 26 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement and under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of these rejections is discussed below.

### Rejections under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 13, 15-16, 19, 23 and 26 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner asserts that the "claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." To satisfy the written description requirement, the written description must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed. In re Gosteli, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Specifically, the Examiner has raised the following rejections.

a. The Examiner asserts that the phrase "neutralization and concentration of the neutralized extract," is new matter "because it does not appear that Applicant disclosed these method steps for the purification of the alkaloid as presented in claim 1." Specifically, the Examiner provides that Magnoflorine and Laurifoline were purified by extraction without any neutralization step, and that "while other species of alkaloids may have been prepared with the method of claim 1, it does not appear that Applicant contemplated neutralization and concentration of the crude extract prior to purification with regard to this particular embodiment."

Claim 13 is drawn to a method for the isolation and purification of an aporphine alkaloid comprising the steps of extracting the ground biomass of a plant containing aporphine alkaloids with a solvent; neutralizing and concentrating the extract and purifying by selected chromatographic methods. Claim 23 is drawn to the method of claim 13 wherein the aporphine alkaloid is selected from Magnoflorine or Laurifoline.

Example 2 describes a method to determine the alkaloid content of different species of Prickly Ash using different methods of extraction. (Specification, pages 15-16). The results are set forth in Table 1. (Specification, page 21). As explained in the Specification, the results obtained from the extractions performed as described in Example 2 demonstrate that isoquinoline alkaloids can be extracted from plants using deionized (DI) water, acidic aqueous solutions or high polarity solvents, such as ethanol, methanol and butanol with or without water. (Specification, page 12, lines 4-7). The Specification further provides that acidic aqueous solutions are the preferred solvents, as they generate high extractable solids and reasonable amounts of isoquinoline alkaloids. (Specification, page 12, lines 7-9). It is also clear from the Specification that in one embodiment of the invention the acidic extract is neutralized prior to chromatography with an aqueous base. (Specification, page 11, lines 21-22). This embodiment is described in Example 2, lines 26-28, which provides that the "solution [acidic extracts of Prickly Ash bark] was filtered through a Buchner funnel, neutralized with NaOH to pH =7 and the solvent evaporated with a freeze-drier." Thus, Applicant maintains that contrary to the Examiner's assertion, extraction with an acidic solvent followed by neutralization was not only contemplated by Applicant, it was demonstrated to be the preferred embodiment of the invention. Applicant therefore respectfully requests that this new matter rejection be withdrawn.

b. The Examiner asserts that the phrase "purification of said extract by a chromatographic method" is also deemed to be new matter within the context of the claim which now recites "consisting of." The Examiner reasons that although claim 13 states "wherein said chromatographic method is selected from the group consisting of ... or a combination of two or more of these methods" it does not appear that Applicant was in possession of the entire scope of the claimed invention which clearly states that only one chromatographic method such as ultra-filtration needs to be used for purification. Specifically, the Examiner notes that both Magnoflorine or Laurifoline were purified on more than one column and it does not appear that Applicant taught or alluded to any method for extracting Magnoflorine or Laurifoline with only one type of chromatographic method.

In response to this rejection claim 13 has been amended to clarify that the method may be used to isolate and purify individual aporphine alkaloids or mixtures thereof. In the case of the isolation and purification of individual compounds two or more columns are generally necessary to achieve the desired level of purity as illustrated in Example 1. It is clear from the Specification however that when a mixture of alkaloids is being isolated one column is sufficient to obtain the desired level of purity. For example, the Specification provides that the crude extract can be purified by various chromatographic methods including "ion exchange chromatography, absorption chromatography, reverse phase chromatography, size exclusive chromatography, ultra-filtration or a combination of two or more of these chromatographic methods." (Specification, page 11, lines 23-27). The Specification also provides that the crude extract can be purified by ultra-filtration or column chromatography to reach the optimum concentration of isoquinoline alkaloids. (Specification, page 12, lines 12-14). Purification of the crude extract on a single column is illustrated in Example 4 (purification on an ion exchange column) (Specification, page 4). Applicant maintains that claim 13, as amended, overcomes this rejection and respectfully requests that this rejection be withdrawn.

Rejections under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 13, 15-16, 19, 23 and 26 under 35 U.S.C. § 112, second paragraph, "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." The second paragraph of Section 112 requires that the claims set out and circumscribe a particular area which applicants regard as their invention with a reasonable degree of precision and particularity. The test of definiteness is whether one skilled in the art would understand the scope of the claim when read in light of the specification. Breadth alone is not indefiniteness. In re Gardner, 166 USPQ 138, 140 (CCPA 1970). Specifically, the Examiner has raised the following rejections.

a. The Examiner maintains that claim 13 recites "consisting of," but it is not clear what this term means within the context of this claim. Specifically, the Examiner provides that

purification by a chromatographic method is a broad concept which typically encompasses dissolving an analyte prior to loading onto the column, eluting into fraction quantities, choosing the fraction of interest and removal of the elution solvent. With respect to this rejection Applicant maintains that when read in light of the Specification, a person of skill in the art would understand that the scope of this claim is limited to the specific chromatographic methods set forth in the claim. The claim clearly describes the steps that are necessary to define the invention. If one conducts a chromatographic separation, that element is met no matter how it is done. Regarding the specific steps involved in a particular chromatographic method, Applicant maintains that when read in light of the Specification and the prior art one of skill in the art would be able to carry out the purification without any degree of uncertainty.

b. The examiner maintains that the term "extraction" is also a broad concept and that it is unclear whether Applicant intends to exclude multiple extraction steps or heating steps. In response to this rejection claim 13 has been amended to clarify that the extraction is being performed with a single solvent system. Regarding the extraction itself it is clear from the Specification, particularly the Examples that the extraction can be performed using solvent that is at ambient temperature or hot solvent. There is no intent to exclude either of these options and Applicant maintains that in light of the Specification there is no uncertainty with respect to the specifics of performing a particular extraction.

c. The examiner maintains that the term "neutralization and concentration of the neutralized extract" is confusing. In response to this rejection, claim 13 has been amended to clarify that the solvent may optionally be acidified and that the acidified solvent may optionally be neutralized prior to purification. As noted above, this amendment is supported on pages 11 and 12 of the Specification, as well as in Example 2.

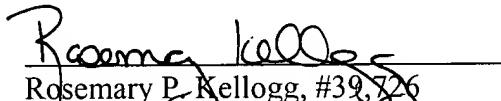
Applicant believes that the pending claims are in condition for allowance. If it would be helpful to obtain favorable consideration of this case, the Examiner is encouraged to call and discuss this case with the undersigned.

Appl. No. 09/741,215  
Amdt. dated February 3, 2004  
Reply to Office Action of November 17, 2004

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-5117, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-5117.

Respectfully submitted,

Date February 3, 2004

  
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